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First introduced into life sciences more than two decades ago as the result of a government settlement, compliance officers and compliance departments are now considered essential for pharmaceutical and medical device companies. Without them, life science companies stand little chance of successfully navigating and managing the legal and

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compliance risks inherent in this highly regulated industry.

However, the life sciences industry is no longer dominated by large market cap companies. Rather, it is a more dynamic and fragmented marketplace populated by numerous smaller, highly focused, and, in many cases, virtual players. These companies are focused on one or two niche areas as opposed to every therapeutic area.

Unlike two decades ago, government guidance, settlements, and precedents outlining the necessary components for effective life science compliance programs abound. Unfortunately, they remain focused predominately on the large company. Little has been done to tailor regulation to this new population of smaller companies.

In February 2012, the U.S. Department of Health and Human Services Office of Inspector General convened a pharmaceutical compliance roundtable with more than 20 chief compliance officers whose companies were under a corporate integrity agreement. The panel's purpose was to discuss implementation challenges during and after a company is subject to such an agreement. Afterward, the OIG published a 13-page report detailing the wide-ranging topics covered in the meeting and touting the meeting's success, although no real discernible changes have emerged in the *last* five years.

Although the government remains steadfast that companies must individually tailor their compliance programs to suit each business and organization, the OIG, among other enforcement bodies, continues to embrace settlement boilerplates and slowly increases the burden and complexity for compliance officers. In January 2017, the OIG published "Measuring Compliance Program Effectiveness: A Resource Guide," a 53-page document on how to assess compliance effectiveness. Despite the OIG's attempt to justify the guide by stating that "any attempt to use this as a standard or a certification is discouraged," the consensus among compliance practitioners is that it's a mandatory, not optional, requirements list.

To make matters worse, these much-touted government guidance, settlements, and precedents do not reflect leading practices. In 2016, the Ethics & Compliance Initiative, or ECI, published the "Principles & Practices of High-Quality Ethics & Compliance Programs," a cross-industry compliance program report. It provided a comprehensive framework for creating high-quality ethics and compliance programs that go beyond regulatory requirements and "become part of the DNA of the organization."

According to the ECI, the key element to achieving such a result is for the program to address rules and ethics together. While corporate


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integrity agreements provide practical frameworks, their purpose is, from an operational compliance perspective, to prevent previous bad conduct and transactions from occurring again. It is a tactical and not a strategic focus. Therefore, the government provides little guidance on how to design and maintain a company culture that encourages ethical decision-making and conduct. Ethics is the critical missing ingredient in corporate integrity agreements, and as a result these documents, so often used as the blueprint for designing life science compliance programs, do not reflect the most current thinking derived from experts across industries.

These developments have given rise to a host of unintended consequences. During a recent industry compliance conference program, experts estimated that a chief compliance officer hired one year before the launch of a commercial drug product would need a staff of four to complete all the necessary compliance elements now required by the government. Smaller companies often either do not believe in the need to adequately invest in “good compliance” or forgo it altogether. Neither outcome is in the public’s best interest. Increasingly, these smaller players are the companies driving industry innovation and the discovery of novel therapies.

It is imperative that the professionals charged with developing compliance programs for small companies understand this paradigm. These professionals must be able to define what “good compliance” looks like for smaller companies. They must be able to articulate a value proposition for investing in compliance that small company CEOs and boards of directors can endorse. But before that can happen, government enforcement agencies must change their mindset and their own measures of success beyond the number and size of settlements.

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